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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/591,233
Filing Date: May 07, 2007
Appellant(s): ERNEBRANT ET AL.

Aaron L. Parker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 22 2011 appealing from the Office action mailed March 22 2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-25 and 29-33 are pending in the application.

Claims 1-25 and 29-33 are rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(**5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading “WITHDRAWN REJECTIONS.” New grounds of rejection (if any) are provided under the subheading “NEW GROUNDS OF REJECTION.”

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant’s brief.

(8) Evidence Relied Upon

5296242	Zander	3-1994
6309673	Duponchelle et al.	10-2001
WO0189478A1	Linden et al.	11-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-7, 11-14, 16-17, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zander (US Patent No. 5296242, cited on PTO Form 1449) in view of Duponchelle et al. (US Patent No. 6309673, cited in the Office action mailed on 9/22/10).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Zander is directed to aqueous solutions and the use thereof. It is taught that bicarbonate-containing dialysis liquids are known. However these solutions are not stable because there is always a risk that carbon dioxide (CO_2) escapes from a bicarbonate solution and consequently the composition of the solution changes (column 1, lines 4-13). In the prior art discussion, Zander indicates prior art which discloses liquid in which in contact with atmospheric air do not change their overall CO_2 content

and which contain certain concentrations of alkali carbonate and alkali bicarbonate. These liquids have a CO_2 partial pressure which corresponds to that of atmospheric air (column 1, lines 55-65). The invention of Zander was to obtain a sterilizable aqueous solution with physiological values of the pH, bicarbonate concentration and CO_2 partial pressure which can be stored in air without requiring special equipment for preventing a diffusing of or in of carbon dioxide (columns 1-2, lines 66-4). It is taught that if pH-value bicarbonate concentration and the CO_2 partial pressure corresponds to the physiological blood plasma levels (pH of 7.4 ± 0.05 and partial pressure of 40 mm Hg) then on using such solutions there is no overdosing or underdosing relative to the acid-base status (column 2, lines 35-50). The invention utilizes two separately stored single solutions to be combined prior to use wherein one is bicarbonate-free acid solution and the other is a bicarbonate-containing alkaline solution (column 2, lines 5-10). The solutions are sterilizable (column 2 lines 30-31). The acid solution can additionally contain calcium and magnesium ions as well as glucose and/or amino acids (column 4, lines 32-35). The exemplified solutions were taught as stable and prevent a diffusing in or out of CO_2 (column 6, lines 42-46). As claimed the sterilizable solution is in the form of two separately stored single solutions which are combinable. One solution is bicarbonate-free acid solution the other is a bicarbonate containing solution comprising alkali bicarbonate and alkali carbonate (claim 1). It is taught that a pH of about 5 prevents denaturation or brown coloration of glucose or amino acids (column 2, lines 30-34).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Zander does not teach the instantly claimed pH values. Zander does not teach the addition of electrolytes to the bicarbonate solution (prior to mixing). Zander does not specify a multi-compartment bag. Zander does not specify the acid is HCl. However, these deficiencies are cured by Duponchelle et al.

Duponchelle et al. is directed to bicarbonate-based solution in two parts for dialysis or continuous renal replacement therapy. It is taught that bicarbonate solutions for injection and for certain types of dialysis need to be sterile. Sterile filtration, steam sterilization, radiation or another suitable sterilization method may be used (column 3, lines 39-61). Multi-compartment containers can be utilized to store and sterilize the solutions (columns 3-4, lines 65-67 and 1-2 and figure 1). The solution utilized is a two-part bicarbonate containing solution. The alkaline bicarbonate solution has a pH adjusted to about 8.6 to 10. The second part is an acidic concentrate having a pH with a range of about 1 to 3. When mixed together the pH of the solution ranges from about 6.5 to 7.6 (column 4, lines 33-44). <u>The pH of the alkaline bicarbonate is chemically adjusted upwards at the time of manufacture to more alkaline values. Chemically increasing the pH of the bicarbonate component upwards when combined with a dextrose component at a low pH yields a stable product that does not need a gas barrier</u> (column 4, lines 45-57). When the bicarbonate possesses this higher pH, the bicarbonate based concentrate is in a steady state and is in equilibrium with the ambient air (column 5, lines 5-10). <u>The multi-chamber container is utilized to store and house the separate solutions</u> (column 5, lines 18-30). The <u>bicarbonate utilized is sodium bicarbonate</u> (table 1). The acidic concentrate contains a physiologically tolerable <u>acid to</u>

adjust the pH. Examples include hydrochloric acid, sulphuric acid, nitric acid etc. (column 7, lines 49-51). It is taught that the problem with utilizing organic acid is that the body has difficulty in metabolizing organic acids and in peritoneal dialysis the presence of organic acids and dextrose enhances the formation of glucose degradation products which in turn may damage the peritoneal membrane, that is why inorganic acids are preferred (column 3, lines 50-58). The pH of the acidic concentrate is chosen so that upon mixing of both the bicarbonate and acidic portions the resulting pH is in a physiologic range (column 7, lines 34-45). The invention can also include an osmotic agent such as glucose or glucose polymers (column 8, lines 1-5 and table 3).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize a pH of the bicarbonate solution that is elevated towards a pH of about 10. One of ordinary skill in the art would have been motivated to utilize an elevated pH of the bicarbonate solution in order to form a solution that does not need a gas barrier. Both Zander and Duponchelle et al. teach that disadvantages of bicarbonate solutions are the escape of CO_2 from the solution. Zander teach utilizing a CO_2 partial pressure that is atmospheric so the solution can be stored in air without requiring special equipment for preventing a diffusing of or in of carbon dioxide, Duponchelle et al. teach utilizing an elevated pH so a gas barrier is not needed. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Zander and Duponchelle et al. and overcome the known art problem of CO_2 concentration and utilize a partial pressure

of CO_2 that is atmospheric and an elevated pH in order to produce a more stable bicarbonate solution that does not need the use of special equipment to keep the CO_2 concentration constant.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize an inorganic acid such as hydrochloric acid to adjust the pH of the acidic solution. One of ordinary skill in the art would have been motivated to utilize an inorganic acid like hydrochloric acid as Duponchelle et al. that the problem with utilizing organic acid is that the body has difficulty in metabolizing organic acids and in peritoneal dialysis the presence of organic acids and dextrose enhances the formation of glucose degradation products which in turn may damage the peritoneal membrane. Therefore, one of ordinary skill in the art based on the teachings of Duponchelle et al. would have been motivated to utilize an inorganic such as hydrochloric acid in order to overcome the problems with organic acids.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize sodium bicarbonate as the source of bicarbonate in the dialysis solution. One of ordinary skill in the art would have been motivated to utilize sodium bicarbonate as Zander teach utilizing alkali bicarbonate and sodium bicarbonate which is exemplified by Duponchelle et al. is a particular type of alkali bicarbonate. It would have been obvious to one of ordinary skill in the art to try the specific alkali bicarbonate, sodium bicarbonate, as a person with ordinary skill has good reason to pursue known options

within his or her technical grasp. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007). It is noted that the use of alkali bicarbonates such as sodium bicarbonate results in electrolytes such as sodium being present in the bicarbonate solution.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize glucose in the solution. One of ordinary skill in the art would have been motivated to utilize glucose as both Zander and Duponchelle et al. teach the addition of this component to the solution. Furthermore, Duponchelle et al. teach that glucose is an osmotic agent. Therefore, one of ordinary skill in the art would have been motivated to add glucose in order to maintain fluid balance (the purpose of an osmotic agent).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander and Duponchelle et al. and utilize a multi-compartment bag to store the solutions. One of ordinary skill in the art would have been motivated to utilize a multi-compartment bag as these are taught by Duponchelle et al. as typical devices utilizes to store these types of solutions. Furthermore, as evidenced by the figure of Duponchelle et al. these bags provide a convenient way to store the multiple solutions in one place which increases ease of use when sterilizing and using.

Regarding the claimed pH of the bicarbonate solution, Duponchelle et al. teach that elevating the pH results in a more stable final solution. The upper limit pH taught is about 10. While the exact pH is not disclosed by Duponchelle et al., it is generally

noted that differences in degree of concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of the bicarbonate pH of the invention and that Duponchelle et al. teach a pH that is substantially similar and Duponchelle et al. and Zander teach a final solution pH which is the same as instantly claimed, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of ranges is the optimum pH.

Regarding the claimed pH of the acidic solution, both Zander and Duponchelle et al. teach utilizing a final solution pH which is physiological (i.e. 6.5 to 7.6). Since the final pH is dependent on the pH of the bicarbonate and the pH of the acidic solution, it would have been obvious to one of ordinary skill in the art to adjust the pH of the acidic solution to a lower pH (such as a pH of 1-3) depending on the starting pH of the bicarbonate solution. Since the use of a higher pH for the bicarbonate is obvious (see above) and Duponchelle et al. teaches that the pH of the acidic concentrate is chosen so that upon mixing of both the bicarbonate and acidic portions the resulting pH is in a physiologic range. It would have been obvious to one of ordinary skill in the art to manipulate the pH of the acidic solution to ensure that the pH of the final solution is physiologic.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 8-10, 15, 18-19, 21-23, 25 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zander in view of Duponchelle et al. and in further view of Linden et al. (WO 0189478, cited in the Office action mailed on 9/22/10).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Zander and Duponchelle et al. are set forth above. Specifically, Zander teach the formation of dialysis solutions wherein the solution is broken into two different solutions wherein one solution is bicarbonate containing and the other is an acidic solution. Duponchelle et al. also teaches a two part dialysis solutions wherein one is bicarbonate containing and the other is acid containing. Both Zander and Duponchelle et al. teach that the two separate solutions are combined for use wherein the resulting pH of the final solution is at physiological pH. Both Zander and Duponchelle et al. teach that glucose can degrade.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Zander does not teach the addition of a third or fourth single solution. Zander does not specify that the sterilization is heat sterilization at a temperature of at least 100 °C. However, these deficiencies are cured by Linden et al.

Linden et al. is directed to medical solution in a multiple compartment container. Linden et al. teaches that scientists have become aware of the toxicity of decomposition compounds of carbohydrates in peritoneal dialyses. Since patient on peritoneal dialysis uses between 8 and 20 liters of dialysis solution every day, depending on the treatment this results in the consumption of 3-7 tons of solution with 1.5-4% glucose every year. If the glucose undergoes decomposition this also means a non-negligible amount of decomposition compounds are consumed. It is well know that some patient experience pain during inflow of dialysis fluid and this pain are believed to be results of glucose degradation (page 1, lines 16-31). The multiple compartment containers comprise at least two compartments, preferably three or more compartments. In at least one of the compartments there is a carbohydrate compound in solution with at least one sulphite compound in one of the compartments to reduce the formation or scavenge already produced decomposition products from the carbohydrate. Commonly used medical solutions either in single or multiple compartment containers contain glucose in the final solution in a concentration in the range of 1.5 to 4% preferably 1.5, 2.5 or 4% (column 6, lines 19-29). As exemplified, one compartment (compartment 44) comprises glucose in 30% and an electrolyte at a pH of 3.2, another compartment (compartment 45) comprises glucose in 50% and an electrolyte at a pH of 3.2 and a third compartment (compartment 9) comprises a bicarbonate and sodium. It is taught if one mixes compartment 44 and 9 you get a final glucose concentration of 1.5%, mixing compartment 45 and 9 gives a glucose concentration of 2.5%, mixing compartments 44, 45 and 9 gives a glucose concentration of 4% (example 1, pages 15-16). Sterilization of

the solutions is performed using conventional sterilization such as heat treatment with a temperature of 100 to 150 °C.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander, Duponchelle et al. and Linden et al. and utilize heat sterilization at a temperature of 100 to 150 °C. One of ordinary skill in the art would have been motivated to utilize heat sterilization at this temperature as Zander teaches the solutions as sterilizable and Duponchelle et al. teach that dialysis solutions must be sterilized before use and one method of sterilization is steam sterilization, therefore, the use of heat sterilization, which is a conventional form of sterilization would have been obvious to one of ordinary skill in the art based on the teachings of Duponchelle et al. and Linden et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander, Duponchelle et al. and Linden et al. and utilize two additional glucose solutions to form the medical solutions for dialysis. One of ordinary skill in the art would have been motivated to utilize two additional glucose solutions in order to manipulate the final glucose concentration as taught by Linden et al. The use of two different glucose solutions allows for the formation of final glucose concentrations of 1.5, 2.5 or 4% which are typical amounts of glucose used in dialysis solutions as taught by Linden et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Zander, Duponchelle et al. and Linden et

al. and utilize a multi-compartment bag for storage of the solutions. One of ordinary skill in the art would have been motivated to utilize a multi-compartment bag as both Duponchelle et al. and Linden et al. teach these are standard bag for housing and use of these types of medical solutions.

Regarding the claimed electrolytes, the exemplified glucose and bicarbonate solutions exemplified by Linden et al. all comprise electrolytes.

Regarding the claimed arrangement of the solutions, Zander, Duponchelle et al. and Linden et al. all teach keeping the solutions separate prior to use. Therefore, based on the teachings of the three references one of ordinary skill in the art would have been motivated to keep the solutions separate in a multi-compartment bag until use and then mixing the solutions to form the final solution.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

(10) Response to Argument

Appellants argue that that (1) the examiner failed to establish a *prima facie* case of obviousness. Appellants argue that Zander and Duponchelle fail to teach all the elements of the claim. Specifically, Appellants argue that Zander and Duponchelle fails to teach that the first single solution has a partial pressure of carbon dioxide of the same order of magnitude as the partial pressure in the atmosphere. Appellants additionally argue that one could not arrive at the instant invention without hindsight. Appellants

argue that (2) Zander and Duponchelle provide one of ordinary skill in the art no reasonable expectation of success.

Regarding appellants first argument, Zander exemplifies a pH of 9.4. The section of Duponchelle pointed to by applicant teaches a pH level of about 9 to 10. Therefore, both are directed to a similar pH. Duponchelle specifically teaches while the adjustment of the pH upward is counter intuitive they found that when this solution is combined with a low pH solution a **stable** product is yielded. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Zander teaches a solution that possesses the same **final** pH as instantly claimed. The two solutions which form the final solution possess the same ingredients as instantly claimed. Zander recognizes keeping the partial pressure of carbon dioxide on the same order of magnitude as the partial pressure of carbon dioxide in the atmosphere. Specifically, Zander teaches that it is known in the art that liquids which

have a CO_2 partial pressure which corresponds to that of atmospheric air do not change their overall CO_2 content. Therefore, there is recognition that the stability can be achieved by maintaining the CO_2 partial pressure of the liquid the same as atmospheric. Since Zander (as pointed out by Applicants in the response filed on 1/21/11, page 3) teaches that carbon dioxide loss leads to bicarbonate solutions that are not stable and that it must be ensured that no CO_2 escapes during storage, wouldn't this suggest to one of ordinary skill in the art to maintain the CO_2 partial pressure to be the same as atmospheric (i.e. no change in CO_2 content). The examiner believes it would. What Zander does not teach is the same starting pH of the solutions. The examiner maintains that Duponchelle teach similar type compositions with pH of the final solution being the same as Zander and instantly claimed and starting pH of the bicarbonate and acid solutions being similar to what is claimed. Therefore, the examiner maintains that it would have been obvious to one of ordinary skill in the art to manipulate the pH of the starting materials to achieve the desired final pH. The instant claims are directed to a product that results from the mixture of a first and second solution (i.e. product by process). The instant claims do not require a particular amount of carbonate or bicarbonate. The instant claim language allows for more steps than just mixing a first and second solution (i.e. claim uses open-ended comprising language). Therefore, the final concentrations of the carbonate and bicarbonate could change depending on what additional steps are added. <u>Thus, the only thing that is truly required by the claims is that the final solution has a pH of 7-7.6 and contains bicarbonate, carbonate and an acid</u>. This is the solution suggested by the combination of references. Assuming

arguendo that the first and second solutions are not exactly the same as instantly claimed, Appellants have not shown that the final medical solution is any different. In fact, the final solution suggested by Zander and Duponchelle possess the same ingredients and the same final pH. Finally, Appellants have not shown that the bicarbonate solution does not possess a partial pressure of carbon dioxide which is in equilibrium with atmospheric carbon dioxide. The specification (page 3 as pointed out to by Appellants) state that “accordingly, the carbonate and bicarbonate concentrations will be stable”. Zander also teaches the compositions were stable. While the examples of the instant specification all teach a carbonate concentration in an amount higher than the bicarbonate concentration, neither the specification or the declaration (filed 1/21/11) shows that this is a requirement to achieve carbon dioxide partial pressures equilibrium. The specification does not show any comparative examples establishing this requirement. Since Zander teaches the obviousness of having partial pressures of carbon dioxide equilibrium, the examiner maintains that manipulation of the bicarbonate and carbonate amounts is obvious.

Regarding appellants second argument, while the examiner acknowledges Zander does not expressly state how much bicarbonate and carbonate would be required to produce a bicarbonate solution that has a carbon dioxide partial pressure that is the same as the atmospheric partial pressure, this is something that one of ordinary skill in the art would easily (or routinely) determine. Clearly the amounts of bicarbonate and carbonate contribute to the pH and carbon dioxide partial pressure values. Therefore, one of ordinary skill in the art would manipulate the amount of

bicarbonate and carbonates to achieve the desired pH and partial pressure. This is something recognized by Zander and Duponchelle. This is tantamount to routine experimentation and one of ordinary skill in the art would have a reasonable expectation of success. Zander does recognize the benefit of stability as it relates to the partial pressure as Zander clearly teaches that problems with these types of solutions in terms of stability is the escaping of carbon dioxide and that carbon dioxide loss leads to bicarbonate solutions that are not stable and that it must be ensured that no CO_2 escapes during storage. Finally, with regards to appellants argument that neither reference recognizes that a particular proportion of bicarbonate/carbonate enables it to be in equilibrium with the partial pressure of carbon dioxide present in the atmosphere, neither does the instant specification. While the examples may show specific amounts of bicarbonate and carbonate which can produce carbon dioxide partial pressure which is in equilibrium with atmospheric carbon dioxide partial pressure, the specification does not expressly recognize what these particular proportions are. The examples teach four different ratios which produce the partial pressure equilibrium (3.19/1, 2.3/1, 4.76/1 and 4.56/1) but doesn't suggest that these are the only proportions are a requirement to achieve the partial pressure. Therefore, the examiner cannot agree that Zander and Duponchelle would not provide a reasonable expectation of success as Zander clearly teaches a desire for achieving an equilibrium in the partial pressure and thee examiner maintains one of ordinary skill in the art would manipulate amounts to achieve this partial pressure.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616

/Jon D. Epperson/

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Conferees:

Abigail Fisher
/A. F./
Examiner, Art Unit 1616